NEOMED incorporated

K072997

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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OFFICIAL CORRESPONDENT	Penny Northcutt, RAC, CQA Regulatory Consultant for NeoMed, Inc. REGSolutions, LLC Tel: 678-428-6978 Fax: 678-513-0937 e-mail: pennynorthcutt@theregsolutions.com
TRADE NAME:	NeoMed Urinary Catheter
CLASSIFICATION NAME:	Urethral Catheter, Urological catheter and accessories
DEVICE CLASSIFICATION AND PRODUCT CODE	Class II per 21 CFR §876.5130 Product Code: 78 GBM
PREDICATE DEVICE NAME	CATCO Urological Catheter (K944782)

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SUBSTANTIAL EQUIVALENCE:

The NeoMed Urinary Catheter is substantially equivalent to the CATCO Urological Catheter cleared under K944782.

Both devices have the same method of operation, drainage of urine through a single lumen catheter. Bench testing has demonstrated that the NeoMed Urinary Catheter is functionally equivalent to predicate urinary catheters currently on the market and that any minor differences do not affect safety or effectiveness.

DESCRIPTION OF THE DEVICE:

The NeoMed Urinary Catheter is a silicone single lumen catheter that is used to drain urine.

The device consists of the following main components: a single lumen urinary catheter, a hub, and a luer lock connector. It is available with either an orange radiopaque stripe or a natural white stripe (supplied from the barium sulfate loaded in the catheter).

INDICATIONS FOR USE:

This product is intended for use in neonatal and pediatric patients to sample urine and/or facilitate urinary drainage. This catheter is NOT a Foley (balloon) type catheter. This catheter is intended for temporary use and will be in contact with the patient for less than 30 days.

PERFORMANCE DATA:

The NeoMed Urinary Catheter materials that come in direct contact with the patient have a long history of use in catheter and urethral catheter manufacture and are biocompatible. Functional test results demonstrate that the NeoMed Urinary Catheter performs its intended use of urine drainage and is equivalent to the predicate device.

CONCLUSION:

Based on the performance testing, it can be concluded that the NeoMed Urinary Catheter is equivalent to the predicate CATCO Urological Catheter with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2007

NeoMed, Inc.
% Ms. Penny Northcutt
Executive Director
REGSolutions, LLC
717 Lakeglen Drive
SUWANEE GA 30024

Re: K072997
Trade/Device Name: NeoMed Urinary Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD and GBM
Dated: October 22, 2007
Received: October 24, 2007

Dear Ms. Northcutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: **NEOMED URINARY CATHETER**

Indications for Use:

The NeoMed Urinary Catheter is intended for use in neonatal and pediatric patients to sample urine and/or facilitate urinary drainage. This catheter is NOT a Foley (balloon) type catheter. This catheter is intended for temporary use and will be in contact with the patient for less than 30 days.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K672997

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)